

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (FDS)

THIS DOCUMENT RELATES TO:)

All Actions)
_____)

**THE NEUROSURGICAL GROUP OF CHATTANOOGA D/B/A
CHATTANOOGA NEUROSURGERY AND SPINE'S OBJECTIONS TO THE
PLAINTIFFS' STEERING COMMITTEE'S SUBPOENA**

Comes the Neurosurgical Group of Chattanooga d/b/a Chattanooga Neurosurgery and Spine ("CNS"), and submits its Objections to Plaintiffs' Steering Committee's ("PSC") subpoena *ad testificandum*, which also requests the production of documents and things. PSC's subpoena should be quashed or modified pursuant to Federal Rules of Civil Procedure 45 and 26. In the alternative, the Court should issue a protective order pursuant to Federal Rule of Civil Procedure 26(c). For the reasons stated below, PSC's subpoena has the following deficiencies:

- PSC failed to provide CNS with the fee for one (1) day's attendance in violation of Federal Rule of Civil Procedure 45(b)(1).
- The subpoena exceeds the scope of the limited discovery approved by the Court.
- The subpoena creates an undue burden and seeks irrelevant information in violation of Federal Rules of Civil Procedure 26(b) and 45.
- The subpoena seeks privileged information in violation of Federal Rule of Civil Procedure 45(c)(3)(A)(iii).

- The subpoena does not provide CNS with a reasonable period of time to comply in violation of Federal Rules of Civil Procedure 45(c)(3) and 34(b)(2)(A).
- PSC has breached its duty to take reasonable steps to avoid undue burden or expense in violation of Federal Rule of Civil Procedure 45(c)(1).

Background

On or about June 17, 2013,¹ PSC served a subpoena upon CNS, which was issued from the United States District Court for the District of Massachusetts and signed by J. Gerard Stranch of the firm Branstetter, Stranch, and Jennings, in Nashville, Tennessee. The subpoena *ad testificandum* scheduled CNS's deposition at the offices of CNS on July 8, 2013, at 9:00 a.m.² Upon service, PSC failed to provide CNS with the fee for one (1) day's attendance in violation of Rule 45(b)(1).

Standard of Review

The Court, under its MDL authority, has the power to issue foreign-district subpoenas pursuant to 28 U.S.C. § 1407(b).⁴ However, when a court exercises its 28 U.S.C. § 1407(b) authority to issue a subpoena to a foreign-district non-party deponent, the MDL judge sits as a judge of the district court where the deponent resides.⁵ In addition, because the MDL judge is acting as a judge of the deponent's district, appeal is to the circuit court of the deponent's district.⁶ In regard to the subpoena issued to CNS, the Honorable Judge Saylor sits as a judge of the United States District Court for

¹ "On or about" is used because the certificate of service, attached to the subpoena, is blank.

² Presumably, the PSC scheduled the deposition for 9:00 EST, but this is not clear from the subpoena.

⁴ *United States ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 444 F.3d 462, 468 (6th Cir. 2006).

⁵ *Id.*

⁶ *Id.* at 469.

⁸ See *Palmer v. Fisher*, 228 F.2d 603, 608-609 (7th Cir. 1955).

the Eastern District of Tennessee and is bound by the precedent of the United States Sixth Circuit Court of Appeals.

Sitting as a judge of the United States District Court for the Eastern District of Tennessee, Judge Saylor must apply the privilege law of the forum state where he sits, Tennessee.⁸

Law and Argument

I. Failure to Issue Proper Service

PSC failed to provide CNS with the \$40.00 fee required upon service of the subpoena.⁹ The plain language of Fed. R. Civ. P. 45(b)(1) is simple. The Fifth Circuit Court of Appeals, quoting the Ninth Circuit Court of Appeals, stated that the correct reading of Fed. R. Civ. P. 45(b)(1) requires little comment.¹⁰ The court stated,

The conjunctive form of the rule indicates that proper service requires not only personal delivery of the subpoena, but also tendering of the witness fee and a reasonable mileage allowance. **“[T]he plain meaning of Rule 45(b)(1) requires simultaneous tendering of witness fees and the reasonably estimated mileage allowed by law with service of a subpoena.” The courts uniformly agree with this interpretation of Rule 45(b)(1), as do the leading treatises on civil procedure.**¹¹

PSC was clearly aware of the need to supply CNS with the applicable fee. The Proof of Service attached to the subpoena that PSC served upon CNS states,

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of \$_____.

My fees are \$_____ for travel and \$_____ for services, for a total of \$_____0.00.¹²

⁹ Fed. R. Civ. P. 45(b)(1); cf. *Vokas Provision Co. v. NLRB*, 796 F.2d 864, 875 (6th Cir. 1986).

¹⁰ *In re Dennis*, 330 F.3d 696, 704 (5th Cir. 2003).

¹¹ *Id.* at 704-705 (emphasis added) (internal citations omitted).

¹² PSC Subpoena (attached as Exhibit 1).

PSC's failure to effect proper service is fatal and cannot be remedied by tendering payment at a later date.¹³ In order to cure this fatal defect, PSC must re-issue the subpoena in compliance with the plain language of Fed. R. Civ. P. 45(b)(1).¹⁴

II. PSC's Breach of the Court's Limitation of Discovery

A. PSC's Breach of the January, 2011 – November, 2012, Timeframe

On June 21, this Court entered two Orders titled: "Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information" ("QPO") and "Order on Central Enforcement of Subpoenas" ("Enforcement Order").¹⁹ The QPO limited the time frame for PSC's subpoena requests, stating,

The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January, 2011 – November, 2012, the patients' last known address, the records identifying that NECC was the supplier of the solution, medication or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.²⁰

In the Enforcement Order, the Court noted that PSC had advised the Court that it intended to issue subpoenas to, "Pain clinics, hospitals, and other entities or individuals who purchased NECC's methylprednisolone acetate, cardioplegic solution, or

¹³ *Aramark Correctional Services, LLC v. County of Cook*, 2012 WL 3792225 (D.S.D. Aug. 31, 2012) (unpublished order).

¹⁴ PSC delinquently tendered the witness fee on Friday, June 28, 2013. As stated, this attempt to remedy PSC's improper service is inadequate.

¹⁹ Dkt. No. 192; Dkt. No. 193.

²⁰ Dkt. No. 192 ¶ 2.

ophthalmic solution.”²¹ Based on PSC’s representations to the Court, the Court’s QPO limited PSC’s subpoena authority, stating,

Plaintiffs’ Counsel are authorized to serve subpoenas issued by this Court on the entities listed in NECC’s Customer list located at: <http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf> as well as Pharmacy Support, Inc., CuraScript, Inc., and Clint Pharmaceuticals.²²

While the Court’s directions to PSC were clear, PSC requested that CNS, an entity not found on the FDA’s list, provide documents and things for a five year period ending on October 6, 2012.²³ PSC has no authority to subpoena CNS, and PSC’s subpoena should be quashed.

B. PSC’s Subpoena Attempts to Circumvent the Court’s Requirement that Protected Health Information be Produced to a Vendor

PSC’s subpoena also violates the Court’s QPO by requesting CNS produce the documents directly to PSC at the deposition.²⁴ The Court clearly ruled that protected health information shall be produced only to a third-party Vendor.²⁵ PSC has prematurely subpoenaed the records of CNS (a non-party and a party not found on the FDA list), because the Vendor has not even been retained by PSC.

C. PSC Did Not Append the QPO to the Subpoenas

The Court ruled that its QPO order “shall be appended to the subpoenas.”²⁶ In its rush to subpoena the records of the non-party CNS, PSC did not append the QPO to the subpoena served on CNS.²⁷

²¹ Dkt. No. 193.

²² Dkt. No. 192 ¶ 10.

²³ PSC Subpoena Exhibit B ¶¶ 1-7, 9, 11. In addition, ¶ 8 asks for all of 2012, ¶¶ 10, 12-21, 24-37 have no time limit, and ¶¶ 22-23 request documents for a three year period. None of PSC’s requests comply with the timeframe limitation of the QPO.

²⁴ PSC Subpoena.

²⁵ Dkt. No. 192 ¶ 3.

²⁶ Dkt. No. 192 ¶ 15.

III. Undue Burden

A. Standard for Undue Burden in the Eastern District of Tennessee

In the Eastern District of Tennessee, when a non-party objects to the relevancy of a request, the court places the burden on the party seeking disclosure to show the relevancy of the requests.²⁸

PSC cannot meet its burden to establish that CNS's testimony is relevant. CNS is not a party to any case related to the fungal meningitis outbreak, let alone any case that has been consolidated in the MDL. The only documents that are relevant to the MDL and possessed by CNS are the protected health records of the plaintiffs in the MDL that received treatment from CNS.²⁹ CNS does not have any documents that would be pertinent to resolving the numerous cases of plaintiffs that were not treated at CNS. Requiring CNS to produce any documents other than the protected health information of the CNS patients in the MDL would be an undue burden to CNS.

When determining whether an undue burden exists, the Eastern District uses factors that include (1) relevance, (2) the need of the party for the documents, (3) the breadth of the document request, (4) the time period covered by it, (5) the particularity with which the documents are described, and (6) the burden imposed.³⁰

The Eastern District also notes that there is some dispute among the courts about whether the issue of burdensomeness should be addressed differently depending

²⁷ PSC furnished the QPO on Friday, June 28, 2013. PSC's delinquent attempt to comply with the Court's QPO does not mitigate the fact that PSC's subpoena was premature.

²⁸ *Travelers Casualty & Surety Company of America v. Pascarella*, 2011 WL 2149524 at *1 n. 1 (E.D. Tenn. May 31, 2011) (unpublished order).

²⁹ CNS does not believe it has any patients in the MDL.

³⁰ *Id.*

on whether the discovery requests are directed to a party or non-party.³¹ However, the Eastern District has always noted whether a subpoena was issued to a party or a non-party, and in *Stratienko*, the court considered the fact that the subpoena was issued to a non-party without explicitly recognizing that it had done so, stating, “[I]n the absence of a showing by the plaintiff that the evidence at issue is actually relevant, not just that it might possibly be relevant, the Court will not allow such discovery, and the accompanying satellite litigation such discovery would entail, as to the personnel files of non-parties. . . .”³²

Therefore, in the Eastern District, once PSC has proved that all of its requests are relevant, CNS must prove that PSC’s requests create an undue burden based on factors including (1) relevance, (2) the need of the party for the documents, (3) the breadth of the document request, (4) the time period covered by it, (5) the particularity with which the documents are described, and (6) the burden imposed. When applied to CNS, the factors weigh overwhelmingly in favor of quashing the subpoena.

B. PSC’s Subpoena is an Undue Burden

First, CNS is not a party to any case in the MDL or any case related to the fungal meningitis outbreak. Consequently, any requests pertaining to the corporate structure of CNS or its insurance policies are completely irrelevant to the claims or defenses in the MDL. The only documents that are relevant to the MDL and possessed by CNS are the protected health records of the plaintiffs in the MDL that received treatment from CNS.³³

³¹ *Id.*

³² *Stratienko v. Chattanooga-Hamilton County Hospital Authority*, 2008 WL 4442492 at *6 (E.D. Tenn. Sept. 25, 2008) (unpublished order) (emphasis added).

³³ CNS does not believe it has any patients in the MDL.

Second, many of the documents requested by PSC are easily obtained from other, more appropriate, sources. PSC requested numerous documents regarding the recall of NECC's medications that can be easily obtained from the FDA, CDC, or Tennessee Department of Health. Furthermore, the overwhelming majority of the documents requested can be easily produced by NECC, an actual party to the MDL. The fact that NECC's bankruptcy case and federal investigation may somehow delay discovery from NECC is no reason to burden Tennessee healthcare providers.

Third, the document requests are prohibitively overbroad, including:

- Any and all documents and/or ESI reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the five-year period immediately preceding October 6, 2012, including patient name, address, date of birth and identification of product administered.³⁴
- Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, during the five-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.³⁵
- Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents [sic], from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, [sic] state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purposes.³⁶

³⁴ PSC Subpoena Exhibit B ¶ 7.

³⁵ PSC Subpoena Exhibit B ¶ 2.

³⁶ PSC Subpoena Exhibit B ¶ 12.

Fourth, PSC's requests fail to seek information during the relevant period of the outbreak and the relevant period of the Court's QPO. The outbreak involved medications that were manufactured by NECC from May through August 2012.³⁷ The requests are also not limited to the timeframe set by the Court: January, 2011 – November, 2012. PSC's five year time period is entirely arbitrary, and PSC has no basis for using such a burdensome timeframe.

Fifth, the documents are broadly requested. PSC has failed to even name CNS in several of the requests, instead referring to CNS as "Healthcare Provider." The requests are not specific as evidenced by the overlap of several requests, and the requests appear to have been sent to parties and non-parties alike, with no concern for the impropriety of treating a non-party like a party. PSC's requests are burdensomely broad, and CNS would require immense time and resources to comply with PSC's requests.

Lastly, PSC's 27 requests for documents are facially burdensome, and it would be cost prohibitive for a non-party to respond to them. As stated previously, PSC has imposed numerous burdens on CNS including:

- Failing to provide CNS with the fee for one (1) day's attendance in violation of Federal Rule of Civil Procedure 45(b)(1);
- Subpoenaing a non-party that is not on the FDA, in violation of the Court's QPO;
- Seeking irrelevant information, including documents related to corporate structure and insurance policies;
- Seeking information pertaining to an irrelevant and arbitrary timeframe,

³⁷<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm323946.htm> (last accessed June 27, 2013).

- To the extent that PSC's requests are overbroad, seeking information privileged by the attorney-client privilege and the work-product doctrine; and
- Failing to provide CNS with a reasonable time to comply.

For all of these reasons, PSC's subpoena should be quashed.

C. PSC's Fishing Expedition

Many of PSC's requests for production, including those identified above, amount to little more than a fishing expedition for potential clients. Fishing for potential clients is completely unrelated to PSC's duty to represent the plaintiffs in the MDL, and a clear burden to CNS.

PSC does not represent a class of all patients who received NECC's medications. Having CNS provide PSC with private health information of patients not in the MDL is nothing more than a fishing expedition, which is prohibited by the Eastern District of Tennessee. In *Stratienko*, the court stated, "Again, the plaintiff cannot state that the [document] is relevant, only that it might be relevant, and the Court will not open the door to a fishing expedition through such private and personal material."³⁸

The protected health information, social security number, name, date of birth, address, and phone number for hundreds, if not thousands, of Tennesseans is also private and personal material.³⁹ Furthermore, the information is completely unrelated to the claims and defenses in the MDL and PSC's duties. PSC has no basis for requesting the documents, and PSC's subpoena should be quashed.

³⁸ *Stratienko*, 2008 WL 4442492 at *6.

³⁹ Dkt. No. 192; PSC Subpoena Exhibit B ¶¶ 7-8.

IV. PSC Seeks Privileged Information in Violation of Fed. R. Civ. P. 45(c)(3)(A)(iii)

To the extent that PSC's requests are overbroad, they seek information that is protected by the attorney-client privilege and the work-product doctrine.

Pursuant to Fed. R. Civ. P. 45(c)(3)(A)(iii), the court must quash or modify PSC's subpoena because it seeks privileged information.

V. PSC Failed to Provide CNS with a Reasonable Period of Time to Comply

PSC has failed to provide CNS a reasonable period of time to comply with its requests for documents. Pursuant to Fed. R. Civ. P. 34(b)(2)(A), a respondent gets 30 days to comply with a request for production. PSC only provided CNS 21 days to respond. Therefore, pursuant to Fed. R. Civ. P. 45(c)(3)(A)(i), the Court must quash or modify the subpoena.

However, even if PSC had provided CNS with 30 days to comply, 30 days is far too short of a timeframe to comply with the overbroad and unduly burdensome requests propounded by PSC.

VI. PSC has Breached its Duty to Take Reasonable Steps to Avoid Undue Burden and Expense

PSC's overbroad and unduly burdensome requests, which fail to provide CNS with a reasonable period of time to respond, and which seek, in part, privileged documents, are a clear violation of PSC's duty to take reasonable steps to avoid undue burden or expense.⁴⁰ Federal Rule of Civil Procedure 45(c)(1) states,

(c) Protecting a Person Subject to a Subpoena

(1) Avoiding Undue Burden or Expense; Sanctions.

A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue

⁴⁰ Fed. R. Civ. P. 45(c)(1).

burden or expense on a person subject to the subpoena. The issuing court must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney’s fees – on a party or attorney who fails to comply.

In light of the fact that PSC has not allowed a reasonable time to respond, exceeded its limited authority, and created an undue burden as defined by the Eastern District of Tennessee, PSC has violated its duty pursuant to Federal Rule of Civil Procedure 45(c)(1).

PSC has also requested documents that are clearly not relevant to any claims or defenses currently before the MDL, including the following requests from Exhibit B of PSC’s subpoena:

- ¶ 19 Any and all documents maintained by CNS related to Tenn. Comp. R. & Regs. R. § 1140-01-.04.
 - Tenn. Comp. R. & Regs. R. § 1140-01-.04 deals with applying for a pharmacy internship license and is inapplicable to CNS.
- ¶ 20 Any and all documents maintained by CNS evincing its compliance with Tenn. Comp. R. & Regs. R. § 1140-01-.05.
 - Tenn. Comp. R. & Regs. R. § 1140-01-.05 deals with licensing examinations for pharmacies and is inapplicable to CNS.
- ¶ 21 Any and all policies of insurance issued to CNS and/or its principal officers and directors and/or any physician working for or on behalf of CNS, for the policy periods including calendar years 2011, 2012 and 2013.
 - Insurance policies of non-parties are irrelevant as stated in *Nix v. Sword*, 11 F. App'x 498, 500 (6th Cir. 2001).
- ¶ 22 Articles of Incorporation and/or By-Laws applicable to CNS for calendar years 2011, 2012 and 2013.
- ¶ 23 Names and addresses of all officers and directors of CNS during 2011, 2012 and 2013.

- ¶ 24 Any and all documents showing entities and individuals with an ownership interest in CNS.
- ¶ 25 Any and all organizational charts and/or documents listing directors, officers, employees, and/or agents of CNS, showing the names and positions of the directors, officers, employees, and/or agents and their relationship or rank within CNS.
- ¶ 26 Any and all documents showing the names of physicians and/or pharmacists that prescribed and/or dispensed NECC products.
 - This request is overbroad.
- ¶ 27 Any and all documents showing the relationship between CNS and the Neurosurgical Group of Chattanooga.

In addition, PSC served CNS with the subpoena before the Court had issued the QPO or Enforcement Order.⁴¹

PSC has breached its duty to avoid imposing undue burden and expense and should be sanctioned pursuant to Federal Rule of Civil Procedure 45(c)(1).

By identifying specific deficiencies in specific paragraphs, CNS does not waive the right to object to other paragraphs, particularly those which request “Any and all documents and ESI reflecting and/or related to...” which are facially overbroad and unduly burdensome.

VII. Conclusion

For the reasons stated herein, CNS requests the Court quash or modify the subpoena in accord with CNS’s objections and impose sanctions against J. Gerard Stranch and PSC.

⁴¹ PSC has breached its duty of good faith by scheduling CNS’s deposition for the same time as four other Tennessee healthcare providers, all of which are represented by Gideon, Cooper & Essary.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

Ct with permission [Signature]
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CERTIFICATE OF SERVICE

This will certify that a true and accurate copy of the foregoing was served on all parties hereto by virtue of the Court's electronic filing system this 1st day of July, 2013.

Ct with permission [Signature]
Chris J. Tardio